

Section 6. MTN-030/IPM 041 Study Product Considerations for Non-Pharmacy Staff

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This section provides information and instructions for non-pharmacy staff related responsibilities for requesting and transporting study product, receiving the MTN-030/IPM 041 vaginal ring (VR) from the site pharmacy, and delivery of the VR to study participants. Record-keeping requirements for non-pharmacy staff also are provided. Associated instructions for pharmacy staff are provided in the MTN-030/IPM 041 Pharmacy Study Product Management Procedures Manual, which will be made available to each MTN CRS Pharmacy by the MTN LOC Pharmacist. Please refer to Section 10 of this SSP manual for product use instructions and guidance on study product adherence counseling.

6.1 Responsibilities and Obligations with Regard to Blinding

MTN-030/IPM 041 Investigators of Record (IoRs), and by delegation all MTN-030/IPM 041 study staff members, are responsible for maintaining the integrity of the study's blinded design. The identity of the specific study product (200mg DPV VR (Ring-104) or 200mg DPV + 320mg LNG (Ring-102)) to which each participant is randomly assigned is double-blinded, meaning that neither study participants nor study staff will be provided information on the identity of the specific study product. During the study implementation period, the SDMC (SCHARP) statisticians will be the only protocol team members unblinded to participant treatment assignment via study randomization.

As described in section 11 of this manual (Data Collection), designated clinic staff will randomize study participants in the study database. Site pharmacy staff – who are excluded from ascertaining primary and secondary study endpoints – will have on-line access (via Medidata) to blinded, coded information indicating the specific study VR to which a participant has been assigned.

Blinding will be maintained throughout the study and until all study endpoint data have been verified and are ready for final analyses. There are no circumstances under which it is expected that unblinding a participant’s study product assignment will be necessary to protect the safety of that individual. In the event that study staff becomes concerned that a participant may be put at undue risk by continuing use of her VR, the IoR may discontinue product use by the participant. However, knowledge of the specific product to which the participant was assigned should not be necessary to guide further follow-up and/or clinical management of the participant.

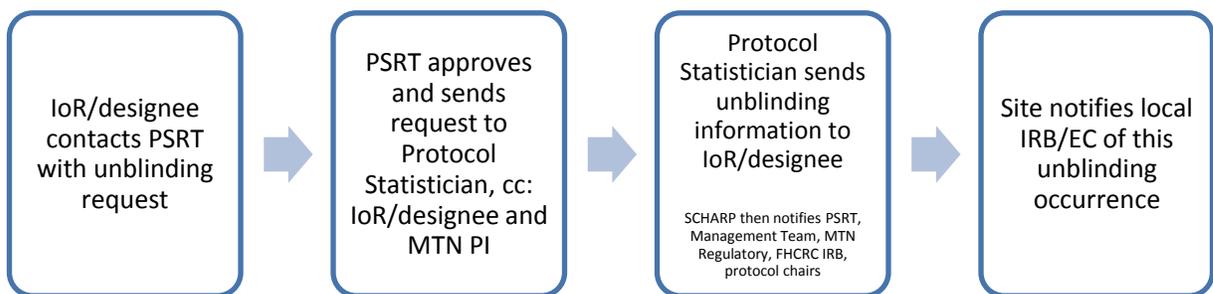
6.1.1 Emergency Unblinding Process

During the trial, an IoR/designee may request that a participant’s study product assignment be provided (unblinding), if essential to protect the participant’s safety.

To request the unblinding for a specific participant, the following steps are required:

1. IoR/designee must contact the MTN-030/IPM 041 Protocol Safety Review Team (PSRT) at mtn030psrt@mtnstopshiv.org.
2. If the PSRT rules that unblinding is required, then the PSRT will send the unblinding e-mail request (with “Unblinding Request” entered in the Subject line) to the Protocol Statistician (Barbra Richardson; barbrar@uw.edu) and cc the IoR/designee from the site so that the statistician can send the information to the correct person(s) at the site. The MTN PI (hillsl@mwri.magee.edu) should also be copied on this request from the PSRT.
3. The Protocol Statistician will provide the study product assignment to the IoR/designee and will then notify the following to let them know that unblinding has occurred: MTN PI, PSRT, the protocol management team and protocol chairs, MTN Regulatory, and the Fred Hutchinson Cancer Research Center IRB.
4. The site IoR/designee must notify the local IRB in an expedited manner of this occurrence of unblinding.

Figure 6-1. Flow Chart of Emergency Unblinding Process



6.2 Randomization Assignment

The MTN Statistical Data Management Center (SDMC) will generate and maintain the study randomization scheme.

Study randomization will occur via the Medidata web-based system, as described in Section 11 (Data Collection) of this manual. After clinic staff have randomized a participant, designated pharmacy staff will have on-line, restricted access (via Medidata) to blinded, coded information that will indicate to the site pharmacist which VR to dispense to the participant. Clinic staff will not have access to this information. Clinic staff will complete a study prescription and send the original part to designated site pharmacy staff, as described in section 6.3 below, to notify the site pharmacist that the participant has been randomized and needs to be dispensed a study VR.

6.3 Prescription Completion and Dispensing Study Vaginal Ring at Enrollment

Each enrolled participant is assigned to a 200mg DPV VR (Ring-104) or 200mg DPV + 320mg LNG (Ring-102) to be worn (vaginally inserted) continuously for 14 days.

An MTN-030/IPM 041 Prescription will be used by clinic staff to request this study product from the site pharmacy at the participant's Enrollment Visit/Visit 2 (see Appendix 6-1). Prescriptions (Appendix 6-1) will be produced as two-part no carbon required (NCR) forms. A bulk supply of prescriptions and request slips will be provided to the clinic staff by the MTN LOC Pharmacy. The MTN LOC Pharmacist should be contacted if additional supplies of the documents are needed during the study.

Each VR will be dispensed directly from the pharmacy to clinic staff on behalf of the participant, upon receipt of an original, written prescription that is signed by an authorized prescriber, as designated in the site's pharmacy dispensing SOP. If staffing issues make it impossible for a clinic staff member to pick up the ring from the pharmacy, a designated transport staff member or runner may pick up the VR and white return bag, and then transfer the VR and bag to a designated clinic staff member who will then provide them to the participant.

Each VR will be dispensed from the pharmacy in its original sealed overwrap – the pharmacist will indicate the PTID and date dispensed on the overwrap label. The pharmacist/designee will also dispense a white VR return bag. The pharmacist/designee will complete the PTID and date the bag was dispensed, and clinic staff will complete a contact name and phone number on the label of the return bag. Clinic staff must be sure to provide the participant with both the VR and the return bag at the Enrollment Visit/Visit 2. This bag may be used for storage if the used VR is removed or expelled (and not reinserted) prior to the next scheduled visit so that it can be returned to the clinic. Although participants are encouraged not to remove the VR, if they do so, they may place it in this bag for storage and ring return as needed. The VR should always be rinsed with clean water only before reinsertion. If the VR will not be reinserted, it should be patted dry with a paper towel and placed in the white VR return bag and returned to the study clinic at the participant's next visit. Participants may request a new bag at clinic visits as needed if the original bag is used or misplaced.

In Clinic Prescription Procedures (C1-C5):

C1. After the participant is randomized, complete an MTN-030/IPM 041 Prescription per instructions on the prescription by recording CRS Name, CRS ID, PTID, and other details. The person who marks the informed consent check box is responsible for confirming the presence of a properly signed/marked and dated informed consent form prior to recording his/her initials beside these boxes.

C2. The middle section of the prescription must be completed by a study staff member designated in the site's delegation of duties as an authorized prescriber of study product. This person also must be listed as an investigator (either the Investigator of Record or Sub-Investigator) on the current FDA Form 1572.

C3. The bottom section of the prescription requires clinic staff initials and the date once all of the above is completed. This should be completed by the clinic staff member who verified that the participant signed the informed consent form and completed the top part of the prescription.

C4. Double-check the accuracy of all entries and then separate the two parts of the completed prescription. Retain the yellow (clinic) copy in the participant study notebook.

C5. Deliver the white (pharmacy) original prescription to the study pharmacy.

In Pharmacy Prescription Procedures (P1-P2):

P1. Upon receiving the completed MTN-030/IPM 041 Prescription, the pharmacist will review the document for completion and accuracy. In the event that a member of pharmacy staff identifies possible errors on the original prescription, he/she will return the original prescription to clinic staff for clarification(s) or correction(s). If corrections are required, corrections must be made on both the white original prescription and the yellow copy. A signed and dated note explaining the corrections also should be recorded on both the white and yellow sheets. The same corrections and notes should be recorded on both the white original and yellow copy, on the same date, by the same person. Corrections to original study prescriptions should only be made by an authorized prescriber and fully documented in the participant's chart notes.

P2. Following review of the signed MTN-030/IPM 041 Prescription, pharmacy staff will dispense the study VR to clinic staff for participant use per instructions in the MTN-030/IPM 041 Pharmacy Study Product Management Procedures Manual and in accordance with the site pharmacy SOP(s).

6.4 Vaginal Ring Request Slip

Once the vaginal ring has been vaginally inserted, the participant should not require additional VRs. Re-supply should be extremely rare – for example, in the event that a clinician/participant drops the ring on a dirty floor prior to insertion, and the pharmacy supplies a new ring. Additionally, in the unusual circumstance that the ring has been removed or expelled during study follow-up and cannot be reinserted, the ring may need to be replaced. In this latter circumstance, the site should consult the MTN-030/IPM 041 PSRT with the details of the participant's situation, and in particular when her next in-clinic PK samples are expected to be collected. The MTN-030/IPM 041 PSRT will provide guidance on whether or not a VR re-supply should occur. In all cases where VR re-supply is deemed necessary, the MTN-030/IPM 041 Vaginal Ring Request Slip should be used (Appendix 6-2). RE-SUPPLY should be marked with the reason for re-supply indicated.

The MTN-030/IPM 041 Vaginal Ring Request Slip can also be used to indicate a clinical (site-initiated) permanent discontinuation of VR use. This includes any time the participant is directed by the clinician to remove the ring prior to the Day 14/Visit 7. Protocol Section 9 (Clinical Management) and SSP Section 7 (Clinical Considerations) specify the circumstances under which use of study product may be permanently discontinued early. For this action, clinic staff should mark the PERMANENT DISCONTINUATION box on the request slip and provide the reason for the study product discontinuation. No further Vaginal Ring Request Slips need to be completed after this visit. A Treatment Discontinuation CRF must also be completed.

For participants who complete the full 14 days of VR use as scheduled, clinic staff should send a request slip marked PRODUCT USE PERIOD COMPLETED to the pharmacy at the Day 14/Visit 7. No further Vaginal Ring Request Slips need to be completed after this visit. A Treatment Discontinuation CRF must also be completed.

The request slip will be produced as two-part no carbon required (NCR) sheets. The top white form is the original (pharmacy), and the bottom form is the copy (clinic). Bulk supplies of the slips are available from the MTN LOC Pharmacist and will be supplied to clinic staff. Clinic staff will complete the CRS Name, PTID, and specified action. The clinic staff name, signature, and signature date must be completed by a clinic staff member authorized to order study product for participants during follow-up.

Double-check the accuracy of all entries and then separate the two parts of the completed slip. Retain the yellow copy in the participant study notebook and deliver the white original to the pharmacy. If corrections are needed, the same corrections must be made separately on both the white original sheet and the yellow copy. A signed and dated note explaining the corrections also should be recorded on both sheets. Identical corrections and notes should be recorded on both copies, on the same date, by the same person.

6.5 Vaginal Ring Accountability

The MTN-030/IPM 041 Study Product Chain of Custody (Pharmacy) SOP provides documentation regarding who receives the VR from the pharmacist. Responsibilities and procedures from the time of product receipt from the pharmacy until delivery to the participant, including procedures for participant identity verification prior to ring provision, should be outlined in the MTN-030/IPM 041 Clinic Study Product Accountability and Destruction SOP. This SOP should be developed with input from both pharmacy and clinic staff to ensure smooth on-site clinic flow. This SOP must be approved by the MTN LOC Pharmacist prior to study activation and may only be modified after consultation with the MTN LOC Pharmacist.

Used VRs will be collected by the clinic staff (rather than the pharmacy). Therefore, accommodation must be made to allow for documentation of distribution, collection, and destruction/removal of study product at the site clinic. A standardized process of tracking and accountability must be followed by all MTN-030/IPM 041 sites. A sample Site-Specific Clinic Study Product Accountability Log is available on the MTN-030/IPM 041 website under Study Implementation Materials. This log includes tracking the date the ring is distributed to the study participant, the date of return of the used ring to the clinic, and the final status of each ring (used ring for storage, used ring for destruction, unused ring to pharmacy, or ring not returned). Sites will be provided an SOP template which should be modified to reflect the specific processes at the site.

6.5.1 Documentation of Vaginal Ring Provision and Collection

Site-Specific Clinic Study Product Accountability Log

This log should be maintained and completed as outlined in the Clinic Study Product Accountability and Destruction SOP. The SOP should define who is responsible for updating this log, when it is updated, where it is stored, how and when it will be QC'd and who is responsible for the QC procedures. It must be updated at least daily and indicated in the Source Document SOP whether any of the data points will collect source data.

Clinic Study Product Destruction Log

This log (also available on the MTN-030/IPM 041 website under Study Implementation Materials) should be completed to document the destruction of the ring in the specific biohazard waste container/bin. This will be the final documentation required for documenting the accountability of any used ring that is not destined for further testing. If a ring is inserted in the clinic and then removed, during the same visit, due to an adverse event or error subsequently discovered, the ring would be placed in the container for destruction.

Specimen Storage CRF

Site staff must document collection and storage of all returned used vaginal rings *that are intended for testing* on the Specimen Storage CRF, as well as the Site-Specific Clinic Study Product Accountability Log.

After documenting the return of used rings on the CRF (if intended for testing) and clinic log, clinic staff should proceed to follow the directions outlined in SSP section 9. The placement of the used ring in the biohazard bag (supplied by MTN Laboratory Center) that is to be stored is documented on the Site-Specific Clinic Study Product Accountability Log.

In the unusual event that a VR was dispensed but never inserted, the unused vaginal ring must be returned to the clinic and the event documented by study staff on a Protocol Deviation Log CRF and on the Site-Specific Clinic Study Product Accountability Log. The unused vaginal ring should be returned to the pharmacy for quarantine. Only unused vaginal rings (never inserted into the vagina) may be returned to the pharmacy. Clinic staff and pharmacy staff will complete the Pharmacy Record of Return of Site-Specific Unused Vaginal Rings.

6.6 Duration of Vaginal Ring Use

Each participant is expected to wear (vaginally inserted) one MTN-030/IPM 041 VR continuously for approximately 14 days. Participants should be counseled to refrain from removing the ring until Visit 7 (Day 14), unless instructed otherwise by site clinic staff. If a participant is unable to complete her Day 14 Visit within the visit window (allowable visit window is study days 13-15, per SSP Section 11), site clinic staff will instruct her to remove the vaginal ring on her own (preferably on Day 15), and bring the used ring with her to the site clinic as soon as she is able. Refer to SSP Section 5.5.3 for further guidance on making up missed Day 14 visit procedures.

6.7 Prohibited and Permissible Medications

Certain medications are prohibited during study participation. Due to potential interactions between levonorgestrel and certain antibiotics and corticosteroids, select antibiotic and corticosteroid use is prohibited. Additionally, pre-exposure prophylaxis (PrEP) and post exposure prophylaxis (PEP) regimens are not permitted during trial participation. Medications listed in Protocol Section 9.3 and the use of PrEP and PEP warrant permanent discontinuation of the study ring. The PSRT must be consulted if a participant uses other prohibited

medication(s). Please refer to Protocol Sections 6.6 and 9.3 and SSP Section 7 for details.

6.7.1 CYP3A4 Inhibitors and Inducers

Participants are prohibited from using CYP3A4 inhibitors and inducers, since both dapivirine and levonorgestrel are CYP3A4 substrates – they are metabolized by CYP3A4. Study staff must promote the avoidance of CYP3A4 inhibitors and inducers (prescription medications, over-the-counter medications, herbal supplements, and nutritional supplements) via any route of administration during study participation. Appendix 6-3 outlines CYP3A4 inhibitors that participants should avoid using concomitantly in this study. Appendix 6-4 outlines CYP3A4 inducers to be avoided.

Information in Appendices 6-3 and 6-4 is adapted from:

<http://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/druginteractions/abeling/ucm093664.htm#4>

These lists are for guidance and may not be all inclusive. If drug-drug interaction questions arise during the study that cannot be answered by any of the study-related materials provided (protocol, SSP, SOPs), please contact the MTN-030/IPM 041 PSRT (mtn030psrt@mtnstopshiv.org). Medications with unknown interactions will be dealt with on a case-by-case basis with input from the PSRT, as needed.

6.7.2 Other Prohibited Medications –Antibiotics and Corticosteroids

Study staff will counsel participants to avoid the use of antibiotics and corticosteroids via any route of administration. Refer to Appendix 6-5 for a list of antibiotics and corticosteroids for participants to avoid during study participation.

6.7.3 Permissible Medications

Some medications are permitted to be taken during study participation. All prescription medications, over-the-counter preparations, vitamins, nutritional supplements, and herbal preparations will be recorded as concomitant medications. It is important to note that single dose oral fluconazole for the treatment of vaginal fungal infection is permitted. If there are questions about permissible medications that cannot be answered by any of the study-related materials provided (protocol, SSP, SOPs), please contact the MTN-030/IPM 041 PSRT (mtn030psrt@mtnstopshiv.org). Inquiries will be dealt with on a case-by-case basis with input from the PSRT, as needed.

6.8 Vaginal Ring Retrieval

Protocol Section 6.4.3 specifies the circumstances under which the study vaginal ring must be retrieved from participants. Because participants are expected to have the vaginal ring in place when they present for the Day 14/Visit 7 (Product Use End Visit/Early Termination Visit), the need for product retrieval is expected to be rare. When product retrieval is required, it is expected that the participant will go to the site clinic to return the ring to site clinic staff.

The VR must be retrieved and returned to the clinic within 24 hours when study product use has been permanently discontinued due to potential or known HIV infection or pregnancy. The VR must be retrieved within 5 working days following permanent discontinuation of study product use (early or scheduled) from the study for any other reasons, as specified in Protocol Section

9.3. If the VR is not returned within these time frames, clinic staff must notify the MTN-030/IPM 041 PSRT and complete a Protocol Deviation Log CRF.

The retrieved vaginal ring must be documented by clinic staff on the Specimen Storage CRF and the Site-Specific Clinic Study Product Accountability Log. If the vaginal ring cannot be retrieved (i.e., participant disposed of it or it was lost after removal), this must be documented on the Protocol Deviation Log CRF and the Site-Specific Clinic Study Product Accountability Log. Related details and counseling around the need to ensure return of study product to site should be detailed in the participant's chart notes.

6.9 Vaginal Ring Complaints

During the study, a problem or concern may be observed with a VR. A problem may be noted by the pharmacy staff, clinic staff, or the participant. These complaints may be about the dosage form (vaginal ring), packaging (overwrap pouch), or other aspects of the study product. Clinic staff should make thorough record of complaints of participants and clinic staff. The clinic staff member will notify (via email) the site PoR and other designated site pharmacy staff of the study product complaint. This notification should include as much detail as possible. The following information should be provided in the email: PTID, date of the observed issue, date that the issue was reported, date VR was dispensed, whether an adverse event occurred, description of the nature of the issue, pictures (if relevant), and any other details deemed necessary.

The site PoR will forward (via email) this information to the MTN LOC Pharmacist. The MTN LOC Pharmacist will forward the study product complaint to IPM. If the complaint/issue is concerning an unused VR, then the unused VR should be quarantined in the pharmacy. If the complaint/issue is concerning a used VR, then the clinic staff should process/store the VR per SSP Section 9.

Appendix 6-2: MTN-030/IPM 041 Vaginal Ring Request Slip

CRS Name: _____
Participant ID <div style="display: flex; align-items: center; gap: 10px;"> <div style="border: 1px solid black; width: 25px; height: 25px; display: inline-block;"></div> <div style="border: 1px solid black; width: 25px; height: 25px; display: inline-block;"></div> <div style="border: 1px solid black; width: 25px; height: 25px; display: inline-block;"></div> - <div style="border: 1px solid black; width: 25px; height: 25px; display: inline-block;"></div> <div style="border: 1px solid black; width: 25px; height: 25px; display: inline-block;"></div> <div style="border: 1px solid black; width: 25px; height: 25px; display: inline-block;"></div> <div style="border: 1px solid black; width: 25px; height: 25px; display: inline-block;"></div> <div style="border: 1px solid black; width: 25px; height: 25px; display: inline-block;"></div> <div style="border: 1px solid black; width: 25px; height: 25px; display: inline-block;"></div> </div> <p style="font-size: 0.8em; margin-top: 5px;">Clinic Staff Instructions: Mark whether this is a study vaginal ring re-supply, clinical permanent discontinuation, or product use period completion notification. Deliver the original white copy (labeled "Pharmacy") to the pharmacy. File the yellow copy (labeled "Clinic") in the participant's study notebook.</p>
<input type="checkbox"/> RE-SUPPLY → Reason: _____ <div style="text-align: center; margin-top: 5px;">Pharmacy: Dispense 1 vaginal ring.</div>
<input type="checkbox"/> PERMANENT DISCONTINUATION → Reason: _____ <div style="text-align: center; margin-top: 5px;">Pharmacy: Do not dispense any further vaginal rings to the participant.</div>
<input type="checkbox"/> PRODUCT USE PERIOD COMPLETED → Pharmacy: Do not dispense any further vaginal rings to the participant.

Clinic Staff Name (please print): _____

Clinic Staff Signature: _____

Date: / /
dd MMM yy

Appendix 6-3: CYP3A4 Inhibitors to Avoid

Strong Inhibitors ≥ 5-fold increase in AUC or > 80% decrease in CL	Moderate Inhibitors ≥2 but < 5-fold increase in AUC or 50-80% decrease in CL	Weak Inhibitors ≥ 1.25 but < 2-fold increase in AUC or 20-50% decrease in CL
<p><u>Antibiotics:</u> clarithromycin, telithromycin</p> <p><u>Antidepressants:</u> nefazodone</p> <p><u>Azole Antifungals:</u> ketoconazole, itraconazole, posaconazole, voriconazole</p> <p><u>Pharmacokinetic Enhancers:</u> cobicistat</p> <p><u>Protease Inhibitors:</u> ritonavir, indinavir, lopinavir/ritonavir, nelfinavir, saquinavir, boceprevir, telaprevir</p> <p><u>Reverse Transcriptase Inhibitors:</u> delavirdine</p> <p><u>Vasopressin Receptor Antagonists:</u> conivaptan</p>	<p><u>Antiarrhythmics:</u> dronedarone</p> <p><u>Antibiotics:</u> erythromycin, ciprofloxacin</p> <p><u>Antiemetics:</u> aprepitant</p> <p><u>Antineoplastics:</u> imatinib</p> <p><u>Azole Antifungals:</u> fluconazole, miconazole</p> <p><u>Calcium Channel Blockers:</u> verapamil, diltiazem</p> <p><u>Protease Inhibitors:</u> atazanavir, darunavir/ritonavir, fosamprenavir</p>	<p><u>Antiandrogens:</u> bicalutamide</p> <p><u>Antianginals:</u> ranolazine</p> <p><u>Antiarrhythmics:</u> amiodarone, quinidine</p> <p><u>Antibiotics:</u> azithromycin</p> <p><u>Antidepressants:</u> fluoxetine, fluvoxamine</p> <p><u>Antihyperlipidemics:</u> atorvastatin</p> <p><u>Anti-inflammatory (asthma):</u> zileuton</p> <p><u>Antineoplastics:</u> nilotinib</p> <p><u>Antituberculars:</u> isoniazid</p> <p><u>Anxiolytics:</u> alprazolam</p> <p><u>Calcium Channel Blockers:</u> amlodipine, felodipine</p> <p><u>Herbal Supplements:</u> ginkgo biloba, goldenseal</p> <p><u>Histamine H2 Antagonists:</u> cimetidine, ranitidine</p> <p><u>Immune Suppressants:</u> cyclosporine</p> <p><u>Platelet Aggregation Inhibitors:</u> cilostazol</p> <p><u>Protease Inhibitors:</u> tipranavir/ritonavir</p>

Appendix 6-4: CYP3A4 Inducers to Avoid

Strong Inducers ≥ 80% decrease in AUC	Moderate Inducers 50-80% decrease in AUC	Weak Inducers 20-50% decrease in AUC
<u>Anticonvulsants/Mood Stabilizers:</u> phenytoin, carbamazepine <u>Anticonvulsants/Barbiturates:</u> primidone <u>Antituberculars:</u> rifampin <u>Barbiturates:</u> phenobarbital, butalbital <u>Glucocorticoids:</u> dexamethasone <u>Herbal Supplements:</u> St. John's wort [^] <u>Protease Inhibitors:</u> tipranavir (alone)	<u>Antibiotics:</u> nafcillin <u>Antihypertensives:</u> bosentan <u>Antituberculars:</u> rifabutin <u>CNS Stimulants:</u> modafinil <u>Reverse Transcriptase Inhibitors:</u> efavirenz, etravirine, nevirapine	<u>Anticonvulsants:</u> oxcarbazepine, rufinamide <u>Antidiabetics:</u> pioglitazone <u>CNS Stimulants:</u> armodafinil <u>Glucocorticoids:</u> prednisone <u>Herbal Supplements:</u> echinacea [^] <u>Protease Inhibitors:</u> amprenavir

[^]The effect of St. John's wort and echinacea varies widely and is preparation-dependent.

AUC: Area under the curve in a plot of concentration of drug in blood/systemic circulation versus time. AUC (from zero to infinity) represents the total drug exposure over time.

CL: Clearance

Appendix 6-5: Prohibited Antibiotics and Corticosteroids

Antibiotic	rifampicin rifabutin cefuroxime axetil cefuroxime sodium ticarcillin/clavulanic acid ampicillin sultamicillin penicillin G penicillin G procaine
Corticosteroid	prednisone prednisolone hydrocortisone